

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., NORTON
(WATERFORD) LTD., and TEVA
PHARMACEUTICALS USA, INC.

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC, AMNEAL IRELAND LIMITED,
AMNEAL PHARMACEUTICALS LLC, and
AMNEAL PHARMACEUTICALS INC.

Defendants.

JOINT DISCOVERY PLAN

**Initial Scheduling Conference:
February 21, 2024 at 3:30 PM**

Civil Action No. 23-cv-20964-SRC-MAH

Electronically Filed

Pursuant to Fed. R. Civ. P. 26(f), L. Civ. R. 26.1, and the Court's January 18, 2024 Order (ECF No. 22), counsel for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Plaintiffs") and counsel for Defendants Amneal Pharmaceuticals of New York, LLC; Amneal Ireland Limited; Amneal Pharmaceuticals LLC; and Amneal Pharmaceuticals Inc. (collectively, "Defendants"), have conferred and respectfully submit the following proposed Joint Discovery Plan, including proposed deadlines for discovery, in advance of the February 21, 2024 Initial Scheduling Conference.

1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.

- (a)** *For Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.:*

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- (b)** *For Defendants Amneal Pharmaceuticals of New York, LLC; Amneal Ireland Limited; Amneal Pharmaceuticals LLC; and Amneal Pharmaceuticals Inc.:*

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2. Set forth a brief description of the case, including the causes of action and defenses asserted.

Plaintiffs’ Description: Plaintiffs brought this Hatch-Waxman action against Defendants on October 6, 2023 (ECF No. 1). In the First Amended Complaint (ECF No. 7), Plaintiffs are alleging claims of patent infringement under the patent laws of the United States arising from Defendants’ submission of Abbreviated New Drug Application (“ANDA”) No. 211600 to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of ProAir[®] HFA (albuterol sulfate) Inhalation Aerosol prior to the expiration of U.S. Patent Nos. 8,132,712 (“the ’712 patent”), 9,463,289 (“the ’289 patent”), 9,808,587 (“the ’587 patent”), 10,561,808 (“the ’808 patent”), and 11,395,889 (“the ’889 patent”) (collectively, “the Patents-in-Suit”). This patent infringement action arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271, the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (“Hatch-Waxman Act”), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

On December 1, 2023, Defendants filed their Answer, Affirmative Defenses, and Counterclaims to Plaintiffs’ First Amended Complaint (ECF No. 12). In their Answer, Defendants deny that Plaintiffs are entitled to the relief they seek. Defendants have also asserted counterclaims for declaratory judgment requiring the delisting of the Patents-in-Suit (Counts 1–5), antitrust violations (Counts 6–10), and declaratory judgments of non-infringement and invalidity (Counts 11–12).

On January 26, 2024, Plaintiffs filed a motion to dismiss Defendants’ counterclaims seeking patent delisting and antitrust violations counterclaims (Counterclaim Counts 1–10, ECF No. 12) with prejudice under Fed. R. Civ. P. 12(b)(6). *See* ECF Nos. 26–27. As outlined in Plaintiffs’ motion, Defendants fail to state a claim requiring delisting of any of the Patents-in-Suit and similarly fail to state a claim for alleged antitrust violations.

Defendants’ Description: In addition to denying liability in their Answer of December 1, 2023 (ECF No. 12), Defendants have filed counterclaims, seeking, *inter alia*, de-listing of the Patents-in-Suit from the FDA’s Orange Book – as Defendants allege the United States Federal Trade Commission has directed Plaintiffs to do. Defendants also assert antitrust counterclaims in connection with the Plaintiff’s wrongful listing of the Patents-in-Suit and wrongful assertion of them in this case. Finally, Defendants have asserted counterclaims for declaratory judgments of non-infringement and invalidity.

On February 20, 2024, Defendants will be filing a motion under Rule 12 for judgment on the pleadings with respect to their counterclaims seeking a de-listing of the Patents-in-Suit from the FDA’s Orange Book – in accordance with the instructions issued to Plaintiffs by the United States Federal Trade Commission.

3. Have settlement discussions taken place?

The parties have engaged in informal settlement discussions directly with each other.

4. The parties have met pursuant to Fed. R. Civ. P. 26(f).

The parties met and conferred on January 22, 2024.

5. The parties have not exchanged the information required by Fed. R. Civ. P. 26(a)(1).

The parties' proposed date for Rule 26(a)(1) disclosures is set forth in the proposed schedule in Exhibit 1.

6. Explain any problems in connection with completing the disclosures required by Fed R. Civ. P. 26(a)(1).

The parties do not anticipate any problems in connection with completing the disclosures required by Fed R. Civ. P. 26(a)(1).

7. The parties have not filed disclosures of third-party litigation funding. *See* L. Civ. R. 7.1.1.

The parties will comply with the requirements of Local Civil Rule 7.1.1.

8. The parties have conducted discovery other than the above disclosures.

Defendants represent that they produced their entire ANDA No. 211600 pursuant to Local Patent Rule 3.6(a) and represent that they have produced FDA correspondence.

9. Proposed joint discovery plan:

(a) Discovery is needed on the following subjects:

Discovery relating to the claims and defenses in the parties' pleadings, including infringement and validity of the Patents-in-Suit, as well as various related issues, claims, affirmative defenses, and counterclaims.

(b) Discovery should be conducted in phases or be limited to particular issues.

To the extent any of Defendants' counterclaims for antitrust violations (Counts 6 to 10) are not dismissed (ECF Nos. 26–27), the parties agree that discovery concerning those antitrust counterclaims should be bifurcated and stayed until after resolution of the claims for patent infringement.

The parties will separately negotiate the schedule and logistics for exchange of discovery

concerning the antitrust counterclaims should the need arise after resolution of the claims for patent infringement.

(c) Proposed schedule:

The parties' proposed schedule is attached hereto as Exhibit 1.

(d) Set forth any special discovery mechanism or procedure requested.

The parties agree that discovery should be conducted in accordance with the parameters set forth in the Federal Rules of Civil Procedure and the Local Rules of this Court except as described below. The limitations below may be revised by agreement of the parties or by order of the Court upon a showing of good cause.

As noted above in Item 9(b), the parties will separately negotiate the schedule and logistics for exchange of discovery concerning the antitrust counterclaims should the need arise after resolution of the claims for patent infringement.

i. Requests for Production:

The parties may serve a maximum of seventy-five (75) Fed. R. Civ. P. 34 requests for production of documents and things on each other.

ii. Requests for Admission:

The parties may serve a maximum of twenty-five (25) Fed. R. Civ. P. 36 requests for admission on each other. For the avoidance of doubt, requests for admission solely regarding the authenticity of documents will not count toward the limit of requests for admission.

iii. Interrogatories:

The parties may serve a maximum of twenty (20) Fed. R. Civ. P. 33 interrogatories, including all discrete subparts, on each other.

iv. Depositions:

The parties may take up to seventy (70) hours of deposition testimony from fact witnesses, including deponents under Fed. R. Civ. P. 30(b)(6) and third parties via subpoena or otherwise.

All fact depositions are limited to a maximum of seven (7) hours total unless extended by agreement of the parties or leave of the Court. Should a deponent testify wholly or substantially through an interpreter (but excluding the use of check interpreters only), each 1.5 hours spent testifying through an interpreter shall count as 1 hour towards the examining party's overall limit for fact depositions. The parties further agree that absent agreement of

the parties or by order of the Court upon a showing of good cause, each fact witness will be deposed only once. The parties will confer on appropriate deviations from these provisions in the case of particular witnesses.

The parties will confer on the most efficient way to proceed with depositions of domestic and foreign witnesses or requests to obtain foreign documents. The parties will cooperate in good faith to schedule depositions at mutually agreeable times and locations.

Absent agreement of the parties or by order of the Court upon a showing of good cause, the parties will exchange notices and objections for depositions pursuant to Fed. R. Civ. P. 30(b)(6) reasonably in advance of the first fact witness deposition requested by the party issuing the notice.

- 10. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of-state witnesses or documents, etc.)?**

The parties may utilize videotape depositions if necessary and agreed upon by the parties. The parties will confer on the most efficient way to proceed with depositions (remote or in person).

- 11. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced?**

No.

- 12. Do you anticipate entry of a Discovery Confidentiality Order? See L. Civ. R. 5.3(b) and Appendix S.**

Yes. The parties agree that a Discovery Confidentiality Order (“DCO”) will be required in this action. The parties’ proposed date for submitting the DCO is set forth in the proposed schedule attached as Exhibit 1. Until the Court enters a DCO in this matter, the parties will follow the confidentiality procedures of L. Pat. R. 2.2.

- 13. Do you anticipate any discovery problem(s) not listed above? Describe.**

No.

- 14. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure**

may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.).

No, the parties do not believe that this case is appropriate for voluntary arbitration, mediation, appointment of a special master, or any other special procedure at this time, but will notify the Court if any parties wish to pursue these options in the future.

15. Is this case appropriate for bifurcation?

As noted above in Item 9(b), to the extent any of Defendants' counterclaims for antitrust violations (Counts 6 to 10) are not dismissed (ECF Nos. 26–27), the parties agree that any discovery related solely to those antitrust counterclaims should be bifurcated until after completion of the claims for patent infringement.

16. An interim status/settlement conference (with clients in attendance), should be held in ____.

A Status Conference before Judge Chesler has been set for March 5, 2024 at 10:00 AM, with trial counsel with full settlement authority along with local counsel to appear in person.

The parties may approach the Court at a later time if they believe another status/settlement conference would be appropriate. The parties will be prepared to discuss this with the Court during the Initial Scheduling Conference.

17. The parties do not consent to the trial being conducted by a Magistrate Judge.

18. Identify any other issues to address at the Rule 16 Scheduling Conference.

None.

18. Pursuant to Local Patent Rule 2.1(a), the parties report the following from the Rule 26(f) conference:

1. Proposed modification of the obligations or deadlines set forth in these Local Patent Rules to ensure that they are suitable for the circumstances of the particular case (*see* L. Pat. R. 1.3).

The parties' proposed schedule, which reflects any proposed modifications, is attached hereto as Exhibit 1.

2. The scope and timing of any claim construction discovery including disclosure of and discovery from any expert witness permitted by the Court.

The parties will submit this information in accordance with the proposed claim construction schedule set forth in Exhibit 1.

3. The format of the Claim Construction Hearing, including whether the Court will hear live testimony, the order of presentation, and the estimated length of the hearing.

The parties will submit this information in the Joint Claim Construction and Prehearing Statement in accordance with the proposed schedule set forth in Exhibit 1.

4. How the parties intend to educate the Court on the patent(s) at issue.

The parties intend to educate the Court on the patents at issue through at least submissions to the Court, which may include presentations during a *Markman* hearing or other tutorial(s).

5. The need for any discovery confidentiality order and a schedule for presenting certification(s) required by L. Civ. R. 5.3(b)(2).

The parties' proposed date for submission of a proposed Discovery Confidentiality Order is set forth in the schedule in Exhibit 1.

6.

a) The availability and timing of production of invention records (including inventor laboratory notebooks and analytical test results).

Plaintiffs are investigating this issue, and intend to provide the information required by the Local Patent Rules in accordance with the schedule set forth in Exhibit 1.

b) The availability and timing of production of ANDA product research and development documents.

Defendants are investigating this issue, and intend to provide the information required by the Local Patent Rules in accordance with the schedule set forth in Exhibit 1.

c) The availability and timing of production of ANDA product samples.

Defendants are investigating this issue, and intend to provide the information required by the Local Patent Rules in accordance with the schedule set forth in Exhibit 1.

d) The date of conception and the date of reduction to practice for each patent asserted in the action, if applicable.

Plaintiffs are investigating conception and/or reduction to practice dates for the Patents-in-Suit. Plaintiffs otherwise intend to provide the documents and information required by the Local Patent Rules with Plaintiffs' contentions as set forth in Exhibit 1.

e) Each inventor's availability for deposition in the matter.

Plaintiffs' investigation regarding each inventor's availability for deposition in this matter is ongoing.

f) Availability of foreign witnesses for deposition and foreign documents.

The parties will confer regarding the availability of foreign witnesses for deposition within the United States and foreign documents, and work in good faith to resolve any disputes relating thereto.

g) Whether there is a 30-month stay and if so, when it ends.

There is a 30-month statutory stay that currently ends on February 28, 2026.

h) A date for substantial completion of document production and a method for determining compliance.

The parties' proposed date for the substantial completion of document production is set forth in the schedule in Exhibit 1.

i) Any other issues or matters that a party believes are time sensitive.

No.

Respectfully Submitted,

Dated: February 16, 2024

/s/ Liza M. Walsh

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EXHIBIT 1 – PROPOSED SCHEDULE

Event	Date
Initial Scheduling Conference	2/21/24 at 3:30 PM
Exchange of Rule 26(a)(1) Initial Disclosures	2/26/24
Plaintiffs Serve Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b)	2/28/24
Status Conference before Judge Chesler	3/5/24 at 10:00 AM
Parties Submit Proposed Discovery Confidentiality Order Pursuant to L. Pat. R. 2.2	3/6/24
Defendants Serve Invalidity Contentions and Accompanying Documents Pursuant to L. Pat. R. 3.6(c)–(d)	3/22/24
Defendants Serve Non-Infringement Contentions and Accompanying Documents Pursuant to L. Pat. R. 3.6(e)–(f)	3/22/24
Plaintiffs Serve Disclosure of Asserted Claims and Infringement Contentions and Accompanying Documents Pursuant to L. Pat. R. 3.6(g)–(h)	5/7/24
Plaintiffs Serve Responses to Invalidity Contentions and Accompanying Documents Pursuant to L. Pat. R. 3.6(i)	5/7/24
Parties Exchange List of Proposed Claim Terms for Construction Pursuant to L. Pat. R. 4.1(a)	5/21/24
Parties Exchange Preliminary Claim Constructions and Identify Intrinsic and Extrinsic Supporting Evidence Pursuant to L. Pat. R. 4.2(a)–(b)	6/10/24
Parties Exchange Identifications of all Intrinsic and Extrinsic Evidence They Intend to Rely Upon in Opposing any Proposed Claim Construction and Thereafter Meet and Confer to Narrow Issues Pursuant to L. Pat. R. 4.2(c)–(d)	6/24/24

Event	Date
Parties File Joint Claim Construction and Prehearing Statement Pursuant to L. Pat. R. 4.3	7/10/24
Completion of Fact Discovery Relating to Claim Construction, including Depositions of Non-Expert Witnesses Identified in Claim Construction Exchanges Pursuant to L. Pat. R. 4.4	8/2/24
Parties Contemporaneously File Opening <i>Markman</i> Submissions Pursuant to L. Pat. R. 4.5(a)	8/14/24
Substantial Completion of Document Production	9/13/24
Completion of Expert Discovery Relating to Opening <i>Markman</i> Submissions Pursuant to L. Pat. R. 4.5(b)	9/13/24
Parties Contemporaneously File Responsive <i>Markman</i> Submissions Pursuant to L. Pat. R. 4.5(c)	9/27/24
Parties Submit Proposed Claim Construction Hearing Schedule Pursuant to L. Pat. R. 4.6	10/4/24
Last Day to Seek to Add New Parties or Amend Pleadings	10/15/24
<i>Markman</i> Hearing	October 2024 (subject to the Court's availability)
Close of Fact Discovery	12/13/24
Exchange of Opening Expert Reports (on issues for which a party bears the burden of proof)	1/29/25
Exchange of Rebuttal Expert Reports	3/14/25
Exchange of Reply Expert Reports	4/8/25
Close of Expert Discovery	5/27/25
Deadline to Request Leave to File Summary Judgment	6/11/25

Event	Date
Submission of Opening <i>Daubert</i> Motions	6/11/25
Submission of Oppositions to <i>Daubert</i> Motions	7/9/25
Submission of Replies to <i>Daubert</i> Motions	7/30/25
Deadline for Filing Joint Pretrial Order	TBD (August 2025)
Pretrial Conference	TBD (August 2025)
Bench Trial	September 2025
30-Month Stay Expiration	2/28/2026